

REMARKS

Claims 1-12 are pending herein. Claims 3-9 stand withdrawn from consideration. Therefore, Claims 1-2 and 10-12 are under review and consideration by the Examiner.

1. Claims 1 and 2 were rejected under 35 U.S.C. §101. Claim 1 has been amended to include the recitation "isolated". Therefore, it is respectfully submitted that Claims 1-2 are in full compliance with §101. Accordingly, it is respectfully requested that the rejection of Claims 1-2 under 35 U.S.C. §101 be withdrawn.

2. Claims 1-2 and 10-12 were rejected under 35 U.S.C. §102(b) over Yoshida et al. publication. For the reasons discussed below, it is respectfully submitted that Claims 1-2 and 10-12 are neither anticipated by nor obvious over Yoshida et al.

The present invention is directed to a domain of gyrase gene responsible for conferring alpha arteether resistance. On the other hand, Yoshida et al. disclose the domain of gyrase gene responsible for conferring quinolone resistance. Yoshida et al. provide the mechanism of quinolone resistance and thereby define the region of the gyrase gene having the effect on resistance and sensitivity to quinolones, but not arteether resistance. It is noted that defining one domain or region of a gene for certain properties does not exclude the possibility of attributing some other property to that domain or region.

In addition, the experiment conducted for the present invention clearly provides the stereospecific inhibition of gyr mutants of *E. coli* by a-arteether (alpha-arteether). The present invention, therefore, indicates that DNA gyrase enzyme alone is involved in conferring a-arteether sensitivity to *E. coli* strains. Hence, the gyrase strains of *E. coli* can be used as biological sensors for detecting the a-isomer of arteether (see page 6, first paragraph, of the application. Also see Tables 3 and 4, providing the mutation sites in gyrase gene for conferring resistance or sensitivity to a-arteether). Yoshida et al. do not indicate any such utility.

Furthermore, the site of mutations disclosed is also different. The present invention provides that the alpha-arteether resistance mutants are the exact reversions at the **87th position of the amino acid of gyrase A subunit**, i.e., Asparagine changed to Aspartic acid, with corresponding change in the codon **AAC to GAC** (mutation A to G) (see page 13, last paragraph, of the application). On the other hand, Yoshida provide Quinolone-resistant *gyrB* point mutations corresponding to amino acid 426 and 447 (nucleotide position 1276 and 1339 of 2412bp *gyrB* coding sequence). For *gyrA* mutation, Yoshida mention the mutation sites as follows:

1. C to T at nucleotide 248, resulting in amino acid change from Ser to Leu at amino acid 83;

2. C to G at nucleotide 248, resulting in amino acid change from Ser to Trp at amino acid 83;
3. G to T at nucleotide 318, resulting in amino acid change from Gln to His at amino acid 106;
4. G to T at nucleotide 199, resulting in amino acid change from Ala to Ser at amino acid 67.

Therefore, Yoshida do not disclose the site of mutation as disclosed in the present application.

Finally, the present invention defines the a-arteether resistance domain from 241 to 261 nucleotide position of Gyr A gene from translation start site. This region corresponds to 81 to 87 amino acid position in the gyrase A peptide.

In view of the above, it is respectfully submitted that none of Claims 1-2 and 10-12 are either anticipated by or obvious over Yoshida et al. publication. Accordingly, it is respectfully requested that the rejection of Claims 1-2 and 10-12 under 35 U.S.C. §102(b) over Yoshida et al. publication be withdrawn.

3. It is further respectfully submitted that since the inventions of Group I (Claims 1-2 and 10-12) and Group III (Claims 5-9) are related as product and process of use, and the product Claims 1-2 and 10-12, as noted above, are allowable, method Claims 5-9 are respectfully requested to be rejoined for examination and allowance.

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Amdt. dated August 3, 2007
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In summary, it is respectfully submitted that Claims 1-2, 5-9 and 10-12 are all allowable.

CONCLUSION

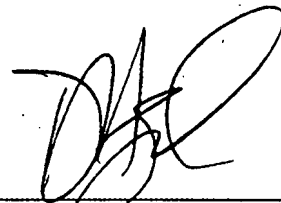
For the foregoing reasons, it is respectfully submitted that Claims 1-2 and 5-12 are in condition for allowance. Withdrawal of all the objections and rejections and allowance of these claims is respectfully solicited.

It is believed that no additional fee is due for this submission. Should that determination be incorrect, however, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

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Should the Examiner have any questions or wish to discuss further this matter,
please contact the undersigned at the telephone number provided below.

Respectfully submitted,



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